

6.0 What is Claimed is:

1 1. At least one implant consisting substantially of cortical bone, said implant comprising
2 a canal surrounded by a continuous or discontinuous wall of cortical bone in the shape of a circle, an
3 ellipse, or an asymmetric shape, thereby forming an implant having a top face and a bottom face,
4 each of which is substantially planar, with said planes being substantially parallel to each other.

1 2. The implant of claim 1 consisting substantially of cortical bone, said implant
2 comprising a canal surrounded by convexly curved anterior cortical bone face and three substantially
3 rectilinear cortical bone faces unitary with said convexly curved anterior cortical bone face.

3 3. The implant of claim 2 which has a substantially "D"-shaped external profile.

4 4. The implant of claim 2 wherein said canal has a substantially "D"-shape.

5 5. The implant of claim 2 further having an external feature on said top face, said
6 bottom face or both.

7 6. The implant of claim 5 wherein said external feature is at least one groove or tooth.

8 7. The implant of claim 6 wherein said external feature is a series of teeth which angle
9 toward said convexly curved anterior face.

1 8. The implant of claim 1 wherein an osteogenic, osteoinductive or osteoconductive
2 composition is packed within said canal.

3 9. The implant of claim 8 wherein said osteogenic, osteoinductive or osteoconductive
4 composition derives from the intervertebral space into which said implant is inserted, is

3 hydroxyapatite, bone powder, bone product, bone morphogenetic protein, bioactive glass, bioactive
4 ceramic, or combinations of these.

1 10. The at least one implant of claim 1 comprising discontinuous walls consisting
2 substantially of cortical bone, wherein said discontinuous walls are mirror image halves which, in
3 combination, form said shape.

1 11. The at least one implant of claim 1 comprising stacked implants consisting
2 substantially of cortical bone, said implants comprising a canal surrounded by a continuous or
3 discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape,
4 thereby forming a stacked implant having a top face and a bottom face, each of which is
5 substantially planar, with said planes being substantially parallel to each other.

1 12. The at least one implant of claim 11 wherein said stacked implants are pinned to each
2 other.

1 13. An implant consisting substantially of at least two shaped cortical bone implants
2 stacked on top of or adjacent to each other.

1 14. The implant of claim 13 wherein said shaped cortical bone implants are adapted to
2 form a unitary implant for implantation into an appropriately dimensioned cavity formed between
3 adjacent vertebrae.

1 15. The implant of claim 14 wherein said cortical bone implants are pinned to each other
2 by cortical bone pins, pins consisting of biocompatible synthetic material or metallic pins.

1 16. The implant of claim 13 wherein said shaped cortical bone implants are two mirror
2 image halves of a desired shape.

1 17. A method of making at least one implant consisting substantially of cortical bone,
2 said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone
3 in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top
4 face and a bottom face, each of which is substantially planar, with said planes being substantially
5 parallel to each other, said method comprising:

- 6 (a) obtaining a plug of bone consisting substantially of cortical bone by using a core cutter
7 having a central drill bit, thereby forming a canal through the bone plug obtained with the
8 core cutter;
9 (b) machining the bone plug of step (a) to produce a "washer-shaped" bone plug;
10 (c) machining the canal through the bone plug to form an asymmetric shape therein; and
11 (d) using said asymmetric shape to machine an outside profile of the bone plug.

12 18. The method of claim 17 wherein said plug of bone is obtained by cutting into the
13 diaphysis of a long bone and into the intramedullary canal of said long bone to form a bone plug
14 having a substantially cortical end and an end derived from the wall of the intramedullary canal.

1 19. The method of claim 18 wherein the end of the plug of bone derived from the
2 intramedullary canal is machined to form a substantially planar surface to obtain a substantially
3 "washer-shaped" bone plug composed substantially of cortical bone.

1 20. The method of claim 19 wherein said canal is formed into an asymmetric shape by
2 broaching said canal to form said asymmetric shape through the bone plug.

1 21. The method of claim 20 wherein said asymmetric shape is substantially "D"-shaped.

1 22. The method of claim 20 wherein said bone plug having a substantially "D"-shaped
2 canal is further machined such that the external profile of the bone plug substantially matches the
3 profile of said canal.

1 23. The method of claim 20 wherein said further machining comprises contacting the
2 bone plug with an asymmetrically shaped grinder wheel.

1 24. The method of claim 20 wherein said further machining comprises mounting said
2 bone plug on a spindle affixed to an asymmetrically shaped cam and contacting the thus mounted
3 bone plug with a cutter rotating about a symmetric axis such that the cutter is made to cut more or
4 less bone as dictated by the shape of said asymmetric cam.

5 25. The method of claim 24 further comprising stacking said bone plug, either prior to or
6 after said machining, drilling holes therein, and pinning said stacked bone plugs to each other.

7 26. A method of making at least one implant consisting substantially of cortical bone,
8 said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone
9 in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top
10 face and a bottom face, each of which is substantially planar, with said planes being substantially
11 parallel to each other, said method comprising:
12

(a) cutting a segment of cortical bone;

(b) shaping said segment of cortical bone into a symmetric half of the final shape of said
implant comprising a canal surrounded by a continuous or discontinuous wall of cortical
bone, such that when implanted in juxtaposition with a mirror image segment, an implant
is formed having a circular, an elliptical, or an asymmetric shape, a top face and a bottom
face, each of which is substantially planar, with said planes being substantially parallel to
each other; and

-30-

(c) cutting appropriate lengths of said shaped segment of cortical bone such that said cut length provides half of an implant having a desired height.

27. The method of claim 17 which further comprises machining an external feature into the top the bottom or both surfaces of the implant.

28. The method of claim 27 wherein said external feature is machined by passing said implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

29. The method of claim 26 which further comprises machining an external feature into the top the bottom or both surfaces of the implant.

30. The method of claim 27 wherein said external feature is machined by passing said implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

31. A broach for forming a canal of desired shape in bone which comprises a plurality of spaced apart rings, wherein the profile of said plurality of spaced apart rings tapers from a first circular ring to a final ring having said desired shape, said taper allowing for removal by each consecutive ring of no more than about 0.004" of bone.

32. An apparatus for forming the external profile of a bone plug having an asymmetric canal, said apparatus comprising (a) a spindle mounted on (b) an asymmetric cam, wherein the shape of said spindle matches the shape of the asymmetric canal of said bone plug so as to allow for a tight mounting of said bone plug onto said spindle, and wherein said asymmetric cam is biased toward (c) a cam follower such that said spindle mounted bone plug is made to contact (d) a cutter means to an extent dictated by the contact of the cam and cam follower such that said cutter fashions an external profile onto the bone plug dictated by the shape of said asymmetric cam.

-31-

1 33. The apparatus of claim 32 comprising:

2 (a) a cross-slide housing a shaft connected to said spindle, to which is also affixed said
3 asymmetric cam;

4 (b) a carriage having a slide-way in which said cross-slide translates in a first, Y-plane, said
5 carriage being slideably mounted on a bed such that said carriage translates in a second,
6 X-plane, transverse to said Y-plane;

7 (c) a cam-follower which limits the translation of said cross-slide in said Y-plane as said
8 asymmetric cam contacts said cam-follower; and

9 (d) a stop means which limits the translation of said carriage in said X-plane at a first,
10 predetermined location of said cutter means which is maintained in rotating register with
11 said spindle-mounted implant.

12 34. The apparatus of claim 33 wherein said cutter means has a "shoulder" thereon
13 defining a radius over which the diameter increases from a first diameter of a cutting surface of said
14 cutter means to a second, greater diameter, of a non-cutting surface of said cutter means.

15 35. The apparatus of claim 34 wherein the advancement of said implant toward the
16 shoulder of said cutter means is limited by said stop, the positioning of which is dictated by a
17 measuring means which is contacted with said implant prior to formation of said external profile,
18 said measuring means dictating the extent of translation of said implant toward said shoulder of said
19 cutter means.

20 36. The apparatus of claim 35 wherein said measuring means provides a first and a
21 second stop position for translation of said implant toward said shoulder, such the external profile of
22 said implant may be fully defined by said cutter as said implant is translated toward said first stop
23 position in which contact with said shoulder is prevented, and then, a bevel is formed on one or
24 more edges of said implant by permitting contact of said implant with said shoulder of said cutter
25 means as said implant is further advanced toward said second stop position.

1 37. An apparatus for forming the external profile of a bone plug having an asymmetric
2 canal, said apparatus comprising (a) a spindle, wherein the shape of said spindle matches the shape
3 of said asymmetric canal of said bone plug so as to allow for a tight mounting of said bone plug onto
4 said spindle, and (b) an asymmetrically shaped grinder wheel which may be brought into contact
5 with said bone plug mounted on said spindle, wherein said grinder wheel and said spindle are
6 maintained in registered contact with each other via a gear such that the rate at which the bone plug
7 rotates in relation to the rate of the rotation of the grinder wheel differs sufficiently to allow abrasion
8 of the surface of the bone plug so as to form an external profile thereon which is dictated by the
9 asymmetry of said grinder wheel.

10 38. A method for inducing fusion of cervical vertebrae which comprises removing a
11 portion of the intervertebral disc between the adjacent vertebrae that are to be fused, and inserting
12 into said space at least one implant consisting substantially of cortical bone, said implant comprising
13 a canal surrounded by a continuous or discontinuous wall of cortical bone in the shape of a circle, an
14 ellipse, or an asymmetric shape, thereby forming an implant having a top face and a bottom face,
15 each of which is substantially planar, with said planes being substantially parallel to each other.

16 39. The method of claim 38 wherein said canal is surrounded by a convexly curved
17 anterior cortical bone face and three substantially rectilinear cortical bone faces unitary with said
18 convexly curved anterior cortical bone face, thereby forming an implant having a top face and a
19 bottom face.

20 40. The method of claim 39 wherein said canal is packed with osteogenic, osteoinductive
21 or osteoconductive material.

22 41. An implant consisting substantially of cortical bone, said implant having been
23 prepared by a process comprising:

- 3 (a) obtaining a plug of bone consisting substantially of cortical bone by using a core cutter
4 having a central drill bit, thereby forming a canal through the bone plug obtained with the
5 core cutter;
6 (b) machining the bone plug of step (a) to produce a "washer-shaped" bone plug;
7 (c) machining the canal through the bone plug to form an asymmetric shape therein; and
8 (d) using said asymmetric shape to machine an outside profile of the bone plug.

1 42. The implant of claim 41 wherein said plug of bone is obtained by cutting into the
2 diaphysis of a long bone and into the intramedullary canal of said long bone to form a bone plug
3 having a substantially cortical end and an end derived from the wall of the intramedullary canal.

4 43. The implant of claim 42 wherein the end of the plug of bone derived from the
5 intramedullary canal is machined to form a substantially planar surface to obtain a substantially
6 "washer-shaped" bone plug composed substantially of cortical bone.

7 44. The implant of claim 43 wherein said canal is formed into an asymmetric shape by
8 broaching said canal to form said asymmetric shape through the bone plug.

1 45. The implant of claim 44 wherein said asymmetric shape is substantially "D"-shaped.

2 46. The implant of claim 44 wherein said bone plug having a substantially "D"-shaped
3 canal is further machined such that the external profile of the bone plug substantially matches the
4 profile of said canal.

5 47. The implant of claim 44 wherein said further machining comprises contacting the
6 bone plug with an asymmetrically shaped grinder wheel.

1 48. The implant of claim 44 wherein said further machining comprises mounting said
2 bone plug on a spindle affixed to an asymmetrically shaped cam and contacting the thus mounted
3 bone plug with a cutter rotating about a symmetric axis such that the cutter is made to cut more or
4 less bone as dictated by the shape of said asymmetric cam.

1 49. The implant of claim 48 further comprising stacking said bone plug, either prior to or
2 after said machining, drilling holes therein, and pinning said stacked bone plugs to each other.

1 50. An implant prepared by a process comprising:

- 2 (a) cutting a segment of cortical bone;
3 (b) shaping said segment of cortical bone into a symmetric half of the final shape of said
4 implant comprising a canal surrounded by a continuous or discontinuous wall of cortical
5 bone, such that when implanted in juxtaposition with a mirror image segment, an implant
6 is formed having a circular, an elliptical, or an asymmetric shape, a top face and a bottom
7 face, each of which is substantially planar, with said planes being substantially parallel to
8 each other; and
9 (c) cutting appropriate lengths of said shaped segment of cortical bone such that said cut
10 length provides half of an implant having a desired height.

1 51. The implant of claim 50 which further comprises machining an external feature into
2 the top the bottom or both surfaces of the implant.

1 52. The implant of claim 41 which further comprises machining an external feature into
2 the top the bottom or both surfaces of the implant.

1 53. An apparatus for inscribing an external feature into a bone implant which comprises:
2 (a) a base having a recess, said recess housing (b) a plurality of cutting blades having both a non-
3 cutting upper surface, against which said bone implant may be pressed, and a cutting upper surface,

4 for inscribing said external feature into said bone implant; said base providing a sliding surface for a
5 (c) carriage; said carriage being slideably fixed to said base by (d) posts holding (e) a guide rod; said
6 carriage further having a (e) tensionable slot for receiving said implant which is loaded into said slot
7 and pushed snugly against said non-cutting upper surface of said plurality of cutting blades, such that
8 said implant may then be raked across said cutting surface of said plurality of blades to inscribe said
9 external feature therein.

1 54. A method of making a substantially cortical bone implant comprising:

- 2 (a) removing the termini of a tibia or femur to produce a diaphysial shaft comprising a natural
3 intra-medullary canal;
4 (b) longitudinally sectioning the anterior margin of the tibia or linea aspera of the femur as close
5 to the intra-medullary canal as possible to produce a shaft of cortical bone of substantially
6 triangular cross-section;
7 (c) cutting said shaft of cortical bone into segments of desired length;
8 (d) drilling a cannulation through a long axis of said segments of cortical bone, wherein said
9 cannulation comprises a bore of such diameter as to leave at least about 2 mm of bone stock
10 between the cannulation and any external side of the cortical bone segment;
11 (e) machining an asymmetry into the cannulation to produce a key way; and
12 (f) further machining the cannulated bone segments utilizing said key way as a means for
13 gripping the cannulated bone segments to produce an implant of desired shape and size
14 characteristics.

1 55. A cortical bone implant produced by the method of claim 54.

1 56. A method of fusing adjacent vertebrae in need thereof which comprises inserting into
2 a space created between said adjacent vertebrae a cortical bone implant according to claim 55.

1 57. The cortical bone implant of claim 55 comprising an osteogenic, osteoinductive or
2 osteoconductive material packed within said cannulation.

-36-

- 1 58. The cortical bone implant of claim 57 wherein said osteogenic, osteoinductive or
2 osteoconductive material comprises a plug of cancellous bone.

0995503.07.1504